

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N-0231]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements obligating holders of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to submit information on adverse drug reactions, lack of effectiveness, and product defects.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA, (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506 (c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2) (A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed reinstatement of an existing collection before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report—21 CFR Part 510 (OMB Control No. 0910-0012)—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)), 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved NADAs submit within 15 working days of receipt, complete records of reports of certain adverse drug reactions and unusual

failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semiannually in a specific format.

This continuous monitoring of approved new animal drugs affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians also using FDA forms 1932 and 1932a. FDA form 2301 is available for the required transmittal of periodic reports and promotional material for new animal drugs. Respondents to this collection of information are applicants of approved NADAs.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2301	510.302(a)	190	13.16	2,500	0.5	1,250
Form FDA 1932	510.302(b)	190	94.74	18,000	1.0	18,000
Form FDA 1932a (voluntary)	510.302(b)	100	1.0	100	1.0	100
Total burden hours						19,350

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Response per Recordkeeper	Hours per Recordkeeper	Total Hours
510.300(a) and 510.301(a)	190	13.16	2,500	10.35	25,875
510.300(b) and 510.301(b)	190	94.74	2,900	0.50	9,000
Total burden hours					34,875

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 5/18/01

May 18, 2001.



Margaret M. Dotzel,

Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE
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